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SPOTLIGHT

Blisters in 1998: New Opportunities Emerge

A series of regulatory developments are likely to result in a growing market for blisters.

by Karen G. Beagley, Midwest Editor

Are blisters booming? Maybe not at this moment, but there are several regulatory and market developments that are pushing many manufacturers toward blisters. While some regulations are expected to expand the blister marketplace, others are likely to encourage companies to reengineer existing blister package designs and employ different materials. In addition, the increased number of clinical trials will probably step up demand for blisters. Without a doubt, blister packaging activity will be amplified in 1998.

CHILD RESISTANT AND SENIOR FRIENDLY

In June 1995, the U.S. Consumer Product Safety Commission (CPSC; Washington) unanimously to issue a final rule modifying the child-resistant packaging test |

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Poison Prevention Packaging Act of 1970. "These changes revise the testing method to make closures adult-friendly and easy to open while maintaining their child-resistant properties," says Richard Ward, vice president and director of consumer product testing at Perritt (Hightstown, NJ). The rule change[s] the makeup of test panels[,] substituting senior adults, aged 60 to 70, for younger adults. This will give a more realistic picture of the ability of normal adults to open child-resistant packaging properly than the current panel of 18 to 45 year olds, according to a statement issued by CPSC.

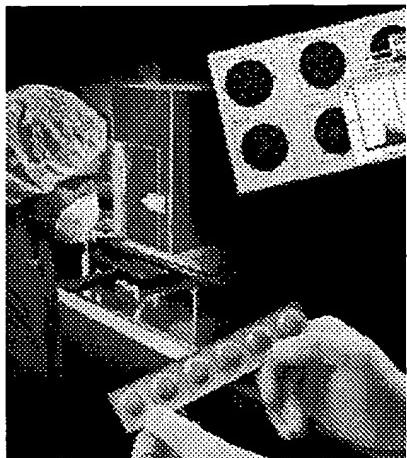


Photo courtesy of Acuity Imaging Inc./Packaging Inc.

The big news now is that as of January 22, 1998, manufacturers began compliance testing using the new senior test panel protocol, which means CPSC representatives can remove packages off the shelves or make establishment of a recall. "This was an important ruling," says Ken Gile, director of pharmaceuticals for CPSC. "Twenty percent of the children being treated with prescription pharmaceuticals were [poisoned by] their grandparents' medicines. The older adult population were not opening and then closing their prescription medicine bottles."

So what can manufacturers do if their blister packages are child-resistant but can't be opened by the senior test panel?

"Manufacturers that have claimed child-resistant packaging have all the child-resistant icons on the package," says Richard Ward, vice president and director of consumer product testing, Perritt (Hightstown, NJ). "Now companies have to deal with the senior test panel. Changes in the directions on the package to read 'Open with scissors' or 'Cut here' enables the package to be opened by the senior test panel. We do not recommend using a scissors icon on a package showing where to cut. A child will recognize that icon, go get the scissors and try to get into the blister. We advocate 'Say it, don't show it.'"

Of course, blister packages will need to be reengineered so they can be cut open with scissors. "I think we need a newer, better design giving an area where the person can cut through the blister and get to the medicine," Ward says.

"Over-the-counter drugs are increasingly coming out in blisters because of the convenience factors," says Dan Gerner, president, Packaging Coordinators of America (Philadelphia).

"There has been a trend toward child resistant even before it was dictated," says Tom Conlon, vice president of sales, Romaco Inc. (Morris Plains, NJ). "Peel-and-pull blister packages are child resistant and now the big issue is to make them senior friendly."

STABILITY TESTING REQUIREMENTS

This past January 1, the International Conference on Harmonisation's (ICH) Technical Guideline for the Requirements for the Regulation of Pharmaceuticals for Human Use took effect. The guidelines deal with stability testing for packages and have been adopted by the U.S. Specifically, the guidelines change the accelerated stability test from 3 months at 40°C, 75% relative humidity to 6 months at 40°C, 75% relative humidity.

The blister industry is taking a variety of approaches to ensure that products will pass the more stringent testing procedures. "We are seeing a trend toward using high-barrier films that will meet these stability testing guidelines," explains Knud A. Christensen, director of pharmaceutical films at Klöckner Pentaplast of America (Princeton, NJ). "The testing conditions are much more severe now. The same drug that passed before may not necessarily pass in the same package under the new stability testing."



An all-aluminum blister package from Teich Packagin

Increasingly, companies are seeking out newer materials that can hold up to rigorous testing procedures. "We are seeing pharmaceutical companies looking seriously at cold-formable foil to meet the more demanding tests," says Dave Hueck, healthcare sales manager, Hueck Foils LLC (Manasquan, NJ).

Burt Zirin, the president of Teich Packaging Inc. (Northbrook, IL), comments: usage of high-barrier cold forming aluminum for moisture-sensitive drugs to n stability-testing guidelines. There are lots of good materials available to meet

However, the ICH requirements are only some of the factors driving companies to alternative materials for blister packaging. "Pharmaceutical companies are changing to meet ICH's guidelines and for other reasons such as price and ease of use. Use of different laminations is becoming more popular," says Bob Misher, executive vice president of Blis-Tech Inc. (Fairview, NJ). "Foil/foil packages have been big in Europe and are coming here."

EUROPEAN MARKET

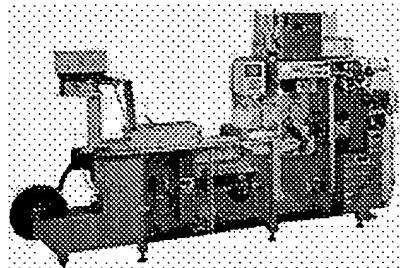
The European market for blisters is larger than that in the United States. "The market uses more blisters than we do, whether they're for prescription or over-the-counter drugs," says Hugh Lockhart, professor, Michigan State University School of Packaging (East Lansing, MI). "They use more-opaque materials, which they claim are less attractive to children. The culture has been more accepting of blisters as the preferred method of packaging."

The European community also has stronger environmental reasons for using blisters. "In Europe, manufacturers are penalized for introducing excessive material into the system. In the U.S., if a blister is cut to a minimal size," says Tom McMurray, director of package engineering, Warner-Lambert (Morris Plains, NJ). "They are just more frugal in their use of materials." Blisters come in the preferred multiple for the specific country. For example, It's multiples of seven."

Another environmental aspect of the widespread use of blisters in Europe is that they are made from PVC. "Europe uses polypropylene for blisters; they feel very strongly about not using PVC because of undesirable by-products you can get as a result of burning PVC," explains Miser.

CLINICAL TRIALS

Another growth area for blisters is clinical trials. With the increasing incidence of chronic diseases, many of which require complex regimens, more pharmaceutical companies are employing blisters. "We use blisters from a convenience and compliance standpoint," says Gary Puzio, clinical supplies manager, Phase IV research group, Schering-Plough (Kenilworth, NJ). "For a dose range study where the patient is taking four tablets a day or more, the only way to do it is in a blister. It is hard to tell a patient to take one tablet from this bottle, then one from this bottle, etc. With a blister, all the medication is there, easily



Romaco Inc.'s blister packaging machine can produce more than 300 blister packs per minute.

One issue that clinical trial companies are considering is whether blister packs are subject to CPSC's child-resistant/senior-friendly regulations. "I have talked with them," says Stan Johnson, chief of integrated quality for the VA Cooperative Studies Program, Clinical Research Pharmacy Coordinating Center (Albuquerque). "They have said that if the package goes into the person's home, then it is subject to the same regulations as other packaging," says Stan Johnson, chief of integrated quality for the VA Cooperative Studies Program, Clinical Research Pharmacy Coordinating Center (Albuquerque). "During most of our studies, the patients take the medications at home. For a limited clinical trial it is not worth the time and expense of conducting child-resistant and senior-friendly features. Previously, the FDA required a provision absolving clinical trials from some of the regulations. With CPSC, there seem to be the latitude we need."

According to CPSC, all medications that end up in a home environment are subject to child-resistant/senior-friendly regulations. "The manufacturer of the package is responsible for the testing to ensure that it is in compliance," says CPSC's Giles. "Pharmaceutical companies must put their products in child-resistant packages, which also must meet the senior-friendly guidelines. A doctor or patient specifically asks for a non-child-resistant package."

IRON SUPPLEMENTS AND THE METHAMPHETAMINE CONTROL ACT

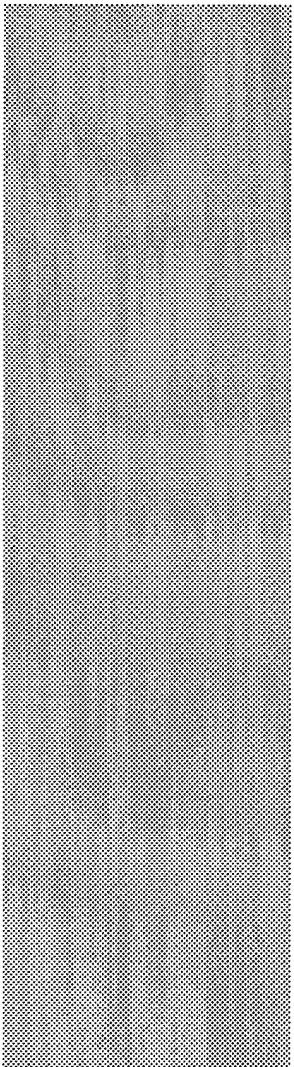
Two regulatory developments relating to iron supplements and methamphetamine manufacturing may affect future growth of blister packaging. FDA's final rule entitled *Iron-Containing Supplements and Drugs: Label Warning Statements and Packaging Requirements* (21 CFR parts 101, 111, and 310), took effect on July 1, 1996. The provision of the ruling calls for unit-dose packaging for iron-containing products containing 30 mg or more of iron per dosage unit.

"There have been some companies that have had to take iron products off the market because they were not in unit-dose packaging," says Matt Neumann, vice president of operations, Uhlmann Packaging Systems (Towaco, NJ). "We are seeing a move toward blisters having to be in compliance. Even though this ruling is already in effect, many companies did not have the time to get their iron into blisters."

On October 3, 1996, President Clinton signed into law the comprehensive Methamphetamine Control Act of 1996. The law broadens control over certain chemicals used in the manufacture of methamphetamine, increases penalties for the trafficking and manufacture of methamphetamine and listed chemicals, and expands regulatory controls to include the distribution of certain lawfully marketed products that incorporate ephedrine, pseudoephedrine (PSE), and phenylpropanolamine (PPA).

The law subjects transactions involving PSE and PPA to the registration, recordkeeping, and reporting requirements of the Controlled Substances Act. The law creates a safe harbor exemption for the retail sale of ordinary over-the-counter products that contain PSE or PPA according to a statement from the Nonprescription Drug Manufacturers Association (Washington, DC).

"In order to be included in the safe harbor, the product must meet two requirements: 1) the package must contain not more than 3 g of the base ingredient, and 2) the product must be in blister packs of not more than two tablets per blister (unless use of the blister



technically impossible, such as for liquids). For those products not packaged in blister packaging, pharmaceutical retailers are required to register with the Drug Enforcement Administration if they sell more than 24 grams per transaction and to keep records of such transactions," according to NDMA's statement.

"Basically, what this means is that if a retailer wants to avoid all the paperwork involved in registering, the retailer should sell the products in blister packaging," says Joe Cipolla, vice president and director of public affairs, NDMA. "The law is designed to stop unscrupulous manufacturers from making illegal drugs from these substances. This would be difficult to have to open each blister package to get the required amount of drug."

CONCLUSION

This year will definitely bring both challenge and opportunity to companies using blister packaging. Packaging engineers have been called upon to develop creative solutions for meeting CPSC's child-resistant, senior-friendly requirements. With additional international developments, such as the ICH testing guidelines and the rule on iron supplement packaging, companies are likely to see more blisters, along with the use of innovative materials and designs.

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